

II. REMARKS

A. Status of the Claims

Claims 1, 3-16, 18-34 were pending at the time of the Action. All of the pending claims were rejected by the Action. Claims 1 and 27 are now amended. Claims 6, 16, 18-26, 28-32, and 34 are cancelled. No new matter is introduced. No new claims are added; therefore, claims 1, 3-5, 7-15, 27 and 33 are currently pending and are presented for reconsideration.

B. The Anticipation Rejection Over Biegajski Is Overcome

The Action maintained its previous anticipation rejection, alleging that all the previously pending claims are anticipated by U.S. 5,700,478 (“Biegajski”). Applicants disagree for the reasons provided in the response filed December 4, 2008 (“the Previous Response”), which is incorporated herein by reference, and the additional reasons described in greater detail below.

Applicants previously noted that Biegajski fails to teach a gel, but instead teaches laminates. Expanding thereon, Applicants further note that Biegajski cannot anticipate claim 1 because the laminated devices taught by Biegajski do not contain a solvent vehicle, which is an element of all the presently (and previously) pending claims. “[I]n order to demonstrate anticipation, the proponent must show ‘that the four corners of a single, prior art document describe every element of the claimed invention.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (citation omitted). The absence of a solvent vehicle is in fact highlighted by the context surrounding the passage of Biegajski cited by the Examiner. In the Office Action dated September 4, 2008 (the Previous Action), the Examiner cites col. 22, line 15 of Biegajski for disclosing Eudragit (polymethacrylate) copolymers. These copolymers are mentioned in the context of possible components of the laminated devices described in Example VII. Applicants note that these devices all **do not** contain a solvent vehicle. In fact, Example VII clearly states: “Where a solvent is a used, the resulting layer is coated on a release

liner and the solvent is allowed to evaporate to produce a dry film.” Biegajski at col. 21, lines 31-34. As such **Biegajski expressly teaches the removal of solvent and therefore fails to anticipate claim 1, or any of its dependent claims.**

Aside from the missing solvent element, Applicants also note that Biegajski does not disclose the remaining elements of claim 1 as arranged as in the claim. The case law is clear on this point. “Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc.*, 545 F.3d at 1369. In maintaining his allegations of anticipation from the Previous Action, the Examiner cites the Abstract of Biegajski at col. 35, line 30 for the drug, Example VII of Biegajski at col. 22, line 15) for Eudragit (polymethacrylate) copolymers, and Example XV of Biegajski at col. 28, lines 40-45 for Carbopol 934. Here different ingredients are being picked from different parts of Biegajski. Even if one were to assume that these three ingredient corresponded to the other three elements of claim 1 (either as presently pending or as previously pending), which Applicants do not concede, then a skilled artisan would still readily recognize that they are still not arranged as in claim 1. They are not even mentioned as part of the same example. The case law is clear on this point: “a reference that discloses all the claimed ingredients, but not in the order claimed, would not anticipate.” *Id.* at 1370.

Finally, the Examiner appears to have misread the Previous Response. Applicants did NOT argue that “claim 1 might be broadly construed to read on laminates and adhesive films,” as the Examiner contends on page 2 of the Action. In fact, Applicants argued that the preamble limits claim 1 to pharmaceutical gels. See the Previous Response at page 7-8, which is incorporated herein by reference. The film coated laminates of Biegajski, therefore, cannot anticipate claim 1 or its dependent claims.

For the above reasons, as well as those presented in the Previous Response, Applicants maintain that Biegajski fails to disclose the pharmaceutical gel of claim 1 or any of its dependent claims. Therefore, Applicants respectfully request that the anticipation rejection be withdrawn.

C. The Obviousness Rejection Over Theramex Is Overcome

The Action alleges that all the previously pending claims are obvious over PCT Patent Publication WO 99/48477 (“Theramex”). Applicants disagree; Theramex does not teach or suggest all the limitations of pending claim 1 as amended. *KSR* demands that “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); see also *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (explaining that an examiner must make “a searching comparison of the claimed invention - **including all its limitations** - with the teaching of the prior art.”) (emphasis added); *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (“obviousness requires a suggestion of all limitations in a claim”) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

Theramex does not teach or suggest at least one limitation of claim 1, namely, a “pH-sensitive **anionic** copolymer of **meth**acrylic acid and **meth**acrylic acid esters, which forms a film when applied to skin or a mucosal surface.” In contrast, Theramex discloses Eudragit L30 D550® and Eudragit RL 100®. Theramex page 7, lines 31-34 and page 8; lines 1-2, respectively. Eudragit RL 100® is a **positively**-charged copolymer of acrylic acid and methacrylate, and Eudragit L30 D550® is an anionic copolymer of methacrylic acid and ethyl **acrylate**. *Id.* Neither the disclosure of Eudragit L30 D550® nor the disclosure of Eudragit RL 100® therefore teaches or suggests the copolymer limitation of the claimed invention. Applicants note that an ethyl acrylate is NOT a type of methacrylic acid ester. Furthermore, Theramex teaches a preference for a copolymer of methacrylic acid and **ethyl** acrylate. See

Theramex, page 8, lines 12-13. A person of skill in the art would, therefore, not be motivated to use a different methacrylic acid copolymer, such as a copolymer of **meth**acrylic acid and **meth**acrylic acid ester, upon reading Theramex. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (“A reference may be said to teach away when a person of ordinary skill, upon reading the reference would be led in a direction divergent from the path that was taken by the applicant.”).

For at least the above reasons, Theramex fails to render obvious the pharmaceutical gel of claim 1 or any of its dependent claims. Therefore, Applicants respectfully request that the obvious rejection over Theramex be withdrawn.

D. The Anticipation Rejection Over Virotex Is Overcome

The Action alleges that all the previously pending claims are anticipated over PCT Patent Publication WO 97/18605 (“Virotex”). Applicants disagree for the following reasons below.

First, Applicants note that Virotex cannot anticipate claim 1 because the laminated devices taught by Virotex does not disclose at least one of the elements of claim 1, namely:

“a solvent vehicle comprising 25 to 100 parts by weight water or buffered water and 0 to 75 parts by weight of ethanol, propylene glycol, glycerin, polyethylene glycol, or combinations thereof, where the solvent vehicle is 100 parts by weight total.”

“[I]n order to demonstrate anticipation, the proponent must show ‘that the four corners of a single, prior art document describe every element of the claimed invention.’” *Net MoneyIN, Inc.*, 545 F.3d 1369. Not only does Virotex NOT teach carrier devices comprising a solvent vehicle, it in fact, **teaches the removal of solvent** prior to the combination of one or more film layers. See especially Examples 1-6, 8-10, 20, 21- 25 and 28, of Virotex, all of which expressly teach or require a prior drying step. For example, many of the Examples of Virotex employ the procedure of Example 1, which clearly teaches drying a “non-adhesive backing layer” for 8-9 minutes at 130 °C. It is noted that the backing layer is dried **before** it is combined with an

adhesive layer. Given the boiling points of water (100 °C), a person of skill in the art would understand that this procedure would effectively remove most if not all of any water that may have initially been present. Virotex confirms this understanding, typically referring to the “dry” and “solid” nature of its carrier devices (*see, e.g.*, Virotex at page 10, line 22, and page 8, line 3, respectively). Furthermore, Virotex contrasts the properties of its carrier devices with those of “bioadhesive gels.” *See* Virotex, paragraph starting at the bottom of page 7 and ending at the top of page 8. The Examiner appears to imply that evaluating some of these compositions in water may supply the missing solvent element, referring to Table 1 and Examples 1, 12 and 17 of Virotex. *See* the Action at page 6. Applicants note that neither Table 1 nor any of these examples present any evaluation results. Instead Table 1 and Example 12 both provide starting material solutions used to make adhesive layers. Example 1, as note above provides a procedure for making a dry backing layer. Example 17 provides a procedure for coating an adhesive solution onto a backing layer. In all cases the end result is a laminate and not a pharmaceutical gel. Examples 19 and 20 of Virotex do provide the results from evaluation studies; however, neither of these examples, either alone or when combined, either expressly or implicitly teach all of the elements of claim 1.

Second, and related to the missing the solvent vehicle, Applicants also note that Virotex does not disclose the other elements of claim 1 arranged as in the claim. The case law is clear on this point. “Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc.*, 545 F.3d at 1369. While Virotex does teach certain bioadhesive polymers and certain film-forming polymers, it consistently discloses them as different layers a of various carrier device, which all appear to be laminates. *See, e.g.*, Example 1 of Theramax at

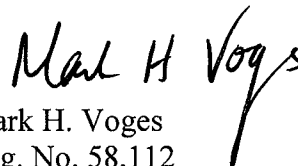
page 20. As noted above and in the Previous Response, a laminate is not a gel. The case law is clear on this point: "a reference that discloses all the claimed ingredients, but not in the order claimed, would not anticipate." *Id.* at 1370. Thus even if Virotext disclosed all the elements of claim 1, which Applicants do not concede, then as a matter of law Virotext cannot anticipate claim 1 unless it also discloses their arrangement in the form of a pharmaceutical gel.

For at least the above two reasons, Virotext does not anticipate claim 1 or any of its dependent claims. Therefore, Applicants respectfully request that this anticipation rejection be withdrawn.

E. Conclusion

In view of the foregoing, it is respectfully submitted that the Application is in condition for allowance. If the Examiner has any questions, he is invited to contact the undersigned attorney at (512) 536-3116.

Respectfully submitted,



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Date: July 10, 2009